In re: Application of Waldemar DEBINSKI et al.

Serial No.: 10/075,499

Examiner: SAKELARIS, Sally A.

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### **REMARKS**

## Restriction Requirement

In the above-identified Office Action, the examiner set forth a restriction requirement and required election of one of the following groups under 35 U.S.C. § 121:

Claims 1-8, drawn to a method of detecting cancer through nucleic acid Group I:

expression detection, classified in class 435, subclass 6.

Claims 1 and 9-12, drawn to a method of detecting cancer through protein Group II:

expression detection, classified in Class 435, subclass 7.1.

Claims 1 and 11-15, drawn to a method of detecting cancer through Group III: expression detection via antibodies, classified in Class 435, subclass 7.1.

Claims 16-19, drawn to a method of modulating Fra-1 gene expression Group IV: with antisense oligonucleotides, classified in Class 514, subclass 44.

Claims 20-26, 28-33, drawn to method of inhibiting VEGF-D gene Group V: expression by introducing a protein as classified in Class 435, subclass 7.1.

Group VI: Claims 20, 26, 27, and 30-33, drawn to a method of inhibiting VEGF-D gene expression by introducing an antisense oligonucleotide as classified in Class 514, subclass 44.

Claims 34-39, drawn to a method of identifying a test compound that Group VII: modulates expression of a Fra-1 gene through detection with a Fra-1 nucleic acid gene marker classified in Class 435, subclass 6.

Group VIII: Claims 34, 36, 40 and 41, drawn to a method of identifying a test compound that modulates expression of a Fra-1 gene through detection with a Fra-1 protein gene marker classified in Class 435, subclass 7.1.

Claims 42-47, drawn to a method of inhibiting angiogenesis by Group IX. administering a protein to interfere with binding classified in Class 514, subclass 12.

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In response, Applicants hereby elect Group VIII (Claims 34, 36, 40 and 41), drawn to a

method of identifying a test compound that modulates expression of a Fra-1 gene through

detection with a Fra-1 protein gene marker classified in Class 435, subclass 7.1. This election is

made without traverse.

The elected claims set forth, herein, are merely to comply with the Restriction

Requirement and is not to be construed as surrender of any subject matter in the instant

application. Applicants hereby reserve the right to pursue the subject matter of the canceled

claims in one or more divisional patent applications. Based on the above election, Applicants

request removal of the restriction requirement and substantive examination of all elected claims.

Applicants invite the Examiner to call the undersigned if it is believed that the above restriction

election is incomplete or improper in any way, or if a telephonic interview will expedite the

prosecution of the application to an allowance.

Dated:

Respectfully submitted,

Gregory A Newson, Reg. No. 30,577

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{WP200343;1}

Docket No. 6460-40



# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450
Alexandris Vindate 2213-1450

PE ARPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
OIV075,499	02/12/2002	Waldemar Debinski	6460-40	8794
1 2 2004 (4)	09/08/2004	•	EXAMI	NER
7590 09/08/2004  A Lanley A. Kim, Ph.D., Esq. Akerman, Senterfitt & Eidson, P.A.  Suite 400			SAKELARIS, SALLY A	
Suite 400	rnt & Eloson, P.A.		ARTUNIT	PAPER NUMBER
722 Lakeview A	venue		1634	
West Palm Beach, FL 33402-3188			DATE MARIED: 00/02/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

SEP : 2004

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# Office Action Summary

Application No.	Applicant(s)	
10/075,499	DEBINSKI ET AL.	
Examiner	Art Unit	
Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -- Period for Reply

THE - External effects - If the - If NC - Failur Any	SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIR IE MAILING DATE OF THIS COMMUNICATION. independent of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, fler SIX (6) MONTHS from the mailing date of this communication. the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum in NO period for reply is specified above, the maximum statutory period will apply and will expire SIX alture to reply within the set or extended period for reply will, by statute, cause the application to be the only reply received by the Office later than three months after the mailing date of this communication, arried patent term adjustment. See 37 CFR 1.704(b).	may a reply be timely filed  m of thirty (30) days will be considered timely. (6) MONTHS from the mailing date of this communication.				
Status						
1)⊠	Responsive to communication(s) filed on 30 September 2002.					
2a)						
3)□	Since this application is in condition for allowance except for forma	I matters, prosecution as to the merits is				
	closed in accordance with the practice under Ex parte Quayle, 193	5 C.D. 11, 453 O.G. 213.				
Dispositi	sition of Claims					
4)⊠	Claim(s) 1-47 is/are pending in the application.	•				
	4a) Of the above claim(s) is/are withdrawn from consideration	on. ~				
5)□	Claim(s) is/are allowed.					
6)[	Claim(s) is/are rejected.					
7)□	Claim(s) is/are objected to.					
.8)⊠	Claim(s) 1-47 are subject to restriction and/or election requirement	•				
Applicati	ation Papers					
9)	☐ The specification is objected to by the Examiner.					
10)	☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ object	ed to by the Examiner.				
	Applicant may not request that any objection to the drawing(s) be held in a	beyance. See 37 CFR 1.85(a).				
	Replacement drawing sheet(s) including the correction is required if the dr	awing(s) is objected to. See 37 CFR 1.121(d).				
11)	$oxedsymbol{\square}$ The oath or declaration is objected to by the Examiner. Note the att	ached Office Action or form PTO-152.				
Priority u	y under 35 U.S.C. § 119					
_	Acknowledgment is made of a claim for foreign priority under 35 U.S  a) All b) Some * c) None of:					
	1. Certified copies of the priority documents have been received.					
	<ul> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li> </ul>					
	application from the International Bureau (PCT Rule 17.2(a)).					
* s	* See the attached detailed Office action for a list of the certified copie					
		•				
Attachment	ent(s)					
1) Notice	otice of References Cited (PTO-892)  4) Interest	rview Summary (PTO-413)				
3) 🔲 Inform		er No(s)/Mail Date ce of Informal Patent Application (PTO-152) er:				
	4 Trademate Office	·				

U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04) Art Unit: 1634

3.

### DETAILED ACTION

### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-8, drawn to a method of detecting cancer through nucleic acid
   expression detection, classified in class 435, subclass 6.
- II. Claims 1 and 9-12, drawn to a method of detecting cancer through protein expression detection, classified in Class 435, subclass 7.1
- III. Claims 1 and 11-15, drawn to a method of detecting cancer through expression detection via antibodies, classified in Class 435, subclass 7.1.
- IV. Claims 16-19, drawn to a method of modulating Fra-1 gene expression with antisense oligonucleotides, classified in Class 514, subclass 44.
- V. Claims 20-26, 28-33, drawn to method of inhibiting VEGF-D gene expression by introducing a protein as classified in Class 435, subclass 7.1.
- VI. Claims 20, 26, 27, and 30-33, drawn to a method of inhibiting VEGF-D gene expression by introducing an antisense oligonucleotide as classified in Class 514, subclass 44.
- VII. Claims 34-39, drawn to a method of identifying a test compound that modulates expression of a Fra-1 gene through detection with a Fra-1 nucleic acid gene marker classified in Class 435, subclass 6.
- VIII. Claims 34, 36, 40 and 41, drawn to a method of identifying a test compound that modulates expression of a Fra-1 gene through detection with a Fra-1 protein gene marker classified in Class 435, subclass 7.1.

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- IX. Claims 42-47, drawn to a method of inhibiting angiogenesis by administering a protein to interfere with binding classified in Class 514 subclass 12.
- 1. The inventions of Groups I-IX are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. Group I is drawn to a method of detecting cancer through nucleic acid expression detection. Group II is drawn to a method of detecting cancer through protein expression detection. Group III drawn to a method of detecting cancer through expression detection via antibodies. Group IV is drawn to a method of modulating Fra-1 gene expression with antisense oligonucleotides. Group V is drawn to method of inhibiting VEGF-D gene expression by introducing a protein. Group VI is drawn to a method of inhibiting VEGF-D gene expression by introducing an antisense oligonucleotide. Group VII is drawn to a method of identifying a test compound that modulates expression of a Fra-1 gene through detection with a Fra-1 nucleic acid gene marker. Group VIII is drawn to a method of identifying a test compound that modulates expression of a Fra-1 gene through detection with a Fra-1 protein gene marker. Finally Group IX is drawn to a method of inhibiting angiogenesis by administering a protein to interfere with binding. The methods all have different method steps, objectives and reagents.

  Therefore the methods are distinct over one another.
- 2. Claim 1 links inventions I-III. Claims 20, 26, and 30-33 link inventions V and VI. Claims 34 and 36 link inventions VII and VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1, 20, 26, 30-33, 34, and 36(respective to each elected group). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or

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otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter and because these inventions require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.
- 4. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris uz ga